



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,424	12/22/2000	Ram Pratap	K&S-0100-US	8031

7590 04/08/2003

Supervisor, Patent Prosecution Services  
PIPER MARBURY RUDNICK & WOLFE LLP  
1200 Nineteenth Street, N.W.  
Washington, DC 20036-2412

EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/742,424

Applicant(s)

PRATAP ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Receipt of amendment filed 10-20-02 and supplemental information disclosure statement filed 2-3-03 is acknowledged. Claims 13-29 have been canceled as requested. In view of the new grounds for rejection, this action is made "non-final."

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-7, 9-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Majeed et al (6,436,991; hereafter '991).

3. '991 discloses compositions and methods comprising administration of an ethyl acetate extract of gum guggul (i.e. guggulipid) to treat memory disorders such as Alzheimer's Disease (AD) (abstract; C 2, L 1-6; C 3, L 31-53; C 4, L 24-48; examples; claims). '991 discloses a dosage level of 0.01-300  $\mu$ M or 0.01 mg/kg to 5 mg/kg. Instant claim 9 requires that a dosage of guggulipid *equivalent* to 40 mg/kg/day for 7 days is administered but does not state what the actual amount is. Since both the instant claims and '991 are directed toward treating memory dysfunctions resulting from Alzheimer's, the dose of '991 is also considered to be equivalent to this dose.

4. '991 does not disclose the instant steps reciting the process by which the gugulipid is obtained, however, in the absence of data these limitations are not afforded patentable weight in that the invention lies in the method of treatment with the compound.
5. Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Majeed et al (6,436,991; hereafter '991) in combination with Standaert and Young (in Goodman and Gilman's, 1996) –see MPEP 2131.01 for multiple 102 rejections.
6. '991 is relied upon for all that it discloses as stated previously. '991 does not disclose that Alzheimer's Disease is an "anticholinergic induced amnesia" as recited in instant claim 8. Standaert and Young is relied upon to show that this is inherent in (AD). Accordingly, '991 also anticipates claim 8.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al (6,436,991; hereafter '991) in view of Reilly, Jr. (in Remington's, 1995).

10. '991 teaches compositions and methods comprising administration of an ethyl acetate extract of gum guggul (i.e. gugulipid) to treat memory disorders such as Alzheimer's Disease (AD) (abstract; C 2, L 1-6; C 3, L 31-53; C 4, L 24-48; examples; claims). While '991 teaches inclusion of pharmaceutically acceptable carriers, diluents and fillers, it does not name specific examples of these.

11. Reilly is relied upon for teaching that the instant claimed additives are known pharmaceutical carriers or fillers.

12. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer the compounds of '991 with an ingredient selected from the group of instant claim 4.

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

Art Unit: 1615

numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
April 5, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600